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10/683,789	10/10/2003	Hoa La Wilhelm	KC-19204	1789

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EXAMINER
YU, MELANIE J

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	**Application No.** 10/683,789	**Applicant(s)** WILHELM ET AL.	
	Examiner Melanie Yu	**Art Unit** 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/27/04*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1-28, it is unclear what type of chemical detection system is on the target substrate.

With respect to claims 1-9 and 20-27, it is unclear how the chemical detection system detects the level of mammalian substance on the target area.

With respect to claims 10-19, it is unclear how the chemical detection system initiates a signal. It is vague and indefinite whether the signal is initiated in response to detection of a mammalian substance.

With respect to claims 12 and 13, it is vague and indefinite how the chemical compositions can initiate a first and second signal comprising a light or a sound.

With respect to claims 3, 5, and 28, it is unclear how the chemical detection system emits a signal. It is vague and indefinite as to whether the emitted signal is initiated by detection.

With respect to claims 20-27, it is unclear whether the second and third chemical compositions detect a respective second and third level of mammalian extract or mammalian substance.

With respect to claim 28, it is unclear how the first and second signals can be compared to quantify the first level of the mammalian substance if the first sub-area emits a first signal in response to the first level, and the second sub-area emits a second signal in response to the first level.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-11, 14-20, 22-24, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Diehl et al. (US 2003/0158530).

Diehl et al. teach a wearable article equipped with a multi-level alert system wherein three or more levels of a mammalian substance in a mammalian extract are detected, the article comprising: a substrate ([0034], lines 1-5); a target area on the substrate including first, second, and third sub-areas for receiving the mammalian extract (area where indicator is applied; [0034], lines 5-18); and a chemical detection system on the target area for detecting a first lower level of the mammalian substance, a second chemical composition in the second sub-area for detecting a second higher level of the mammalian substance, and a third chemical composition in the third sub-area for detecting a third level of the mammalian substance (Fig. 5; Fig. 6; [0028]; [0029], lines 14-39), wherein the chemical detection system comprises a different chemical composition on the first, second, and third sub-areas ([0028]; [0029], lines 14-26). Detection is performed by the chemical composition on the substrate, after which a signal (color change) is initiated and is emitted by each sub-area in response to a respective level of the mammalian substance (Fig. 5; Fig. 6; [0029], lines 22-29). The first and second signals can be compared to quantify the first level of the mammalian substance ([0029], lines 36-42).

Diehl et al. teach the wearable article being a personal care absorbent article (diaper, [0015], lines 20-24), a medical absorbent article (bandage, [0015], lines 20-24), an athletic absorbent article (underwear, [0015], lines 20-24), a nonabsorbent article (belt, [0014], lines 4-11), a garment (underwear, [0015], lines 20-24), or an article of clothing (underwear, [0014], lines 4-11).

Diehl et al. teach the wearable article wherein the first, second, and third sub-areas comprise strips, adjacent shapes, numbers, symbols, letters, or words ([0028], lines 8-11).

2. Claims 10, 12, 13, 21, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Springer et al. (US 6,617,488).

Springer et al. teach a wearable article equipped with a multi-level alert system for detecting, and initiating and emitting a signal in response to three or more levels of a mammalian substance in a mammalian extract, the wearable article comprising: a substrate (col. 8, lines 15-23), a target area on the substrate comprising first, second, and third sub-areas (col. 7, lines 13-20 and 36-39) in the form of concentric shapes (bullseye, col. 10, lines 39-40), and a chemical detection system on the target area which detects and initiates a first, second, and third signal, in response to a respective first, second, and third level of mammalian substance (col. 7, lines 13-20 and 28-35). Springer et al. also teach the chemical compositions in the sub-areas adapted to detect different levels of pH in the mammalian substance (col. 7, lines 13-26).

With respect to claims 12 and 13, Springer et al. teach a wearable article wherein the first and second signal comprise a respective light or a respective sound in response to a level of pH (col. 10, lines 13-20). Spring et al. teach an electrochemical indicator, including a pH sensor, comprising the compositions of the first, second, and third sub-area and an electrochemical cell (col. 8, lines 44-52). The pH sensor provides an electrical signal, such as an electric potential that depends on pH, and emits a visual indication (light) or an audible signal (sound).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diehl et al. (US 2003/0158530) in view of Ponce et al. (Critical Revision of Presumptive Tests for Bloodstains, Forensic Science Communications, Vol. 1, No. 2; July, 1999) further in view of Rittersdorf et al. (US 3,917,452).

Carlucci et al., as disclosed above, teach a wearable article equipped with a multi-level alert system for detecting three or more levels of a mammalian substance, but fail to teach the detection of blood.

Ponce et al. teach semiporous filter paper with a first chemical composition comprising phenolphthalein, a second chemical composition comprising o-tolidine, and a third chemical composition comprising leucomalachite (Materials and Methods, reagents) in order to test for false results in blood detection using reagents that detect different levels of blood in a sample

(Evaluation of the Results, paragraph 3), but fails to provide motivation to include the chemical compositions in the wearable article of Carlucci et al.

However, Rittersdorf et al. teach that the detection of blood in urine, feces, and vomit allows for diagnosis of hemorrhages in the stomach, intestines, and urinary tract (col. 1, lines 8-13 and 30-34).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the wearable article as taught by Carlucci et al., the compositions to detect blood as taught by Ponce et al., in order to provide a multi-level alert system capable of detecting small amounts of blood to diagnose hemorrhages as taught by Rittersdorf et al.

Conclusion

No claims are allowed.

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Carlucci et al. (US 2003/0065299) teach absorbent wearable articles, including sweat pads, comprising a blood detection composition that provide a visual color change in the presence of blood. Jeutter et al. (US 6,583,722) teach a wearable article with a signaling device that indicates a change from a first condition to a second condition by emitting an audible or visible signal. Everhart et al. (US 5,468,236) teach a wearable absorbent product including chemically reactive means to provide a visual indication of the presence of a substance in a mammalian extract.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Y

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10/28/04